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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,761	02/08/2002	Yanggu Shi	PT005P4C1	9814

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,761	SHI ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1, 3, 4, 11 and 12 recite sequence identifiers which are non-descriptive (i.e. SEQ ID NO:X and SEQ ID NO:Y.). Applicant is reminded that when a sequence is recited in the claims or disclosed in the specification, numerical sequence identifiers must be used (see 37 CFR 1.821(d)). Applicant's disclosure (page 41, paragraph 136) indicates that SEQ ID NO: X may be any of the polynucleotides disclosed in the Sequence Listing and SEQ ID NO: Y may be any of the polypeptides disclosed in the Sequence Listing. The Examiner has used this information accordingly for preliminary examination. Applicant is requested to make the appropriate corrections in response to this action. Also the specification (page 40, Table 1) discloses 2-11 nucleic acid for SEQ ID NO: X, and 12-21 polypeptide SEQ ID NO: Y. The restriction has therefore been set forth for each sequence encompassed in SEQ ID NO: X and Y. The Examiner notes that these molecules do not share a substantial structural feature essential to a common utility.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1-10. Claims 1-10 and 14-15, drawn to an isolated nucleic acid molecule of SEQ ID NO:2-11, vectors, host cells, and methods of producing the polypeptide, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.

11-20. Claims 11-12 and 16, drawn to a polypeptide comprising SEQ ID NO:12-21, and fragments thereof; classified in Class 530, subclasses 395, 837, and 866.

21-30. Claim 13, drawn to an antibody that binds specifically to the SEQ ID NO: 12-21; classified in Class 530, subclass 387.3, and 391.1.

31-40. Claims 17, drawn to a method of preventing, treating or ameliorating a medical condition with the polynucleotide of SEQ ID NO: 2-11, classified in Class 514, subclass 44.

41-50. Claims 18, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject by determining the presence or absence of a mutation in the polynucleotide of SEQ ID NO: 2-11, classified in Class 436, subclass 94.

51-60. Claim 19, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition in a subject by determining the presence or amount of expression of the polypeptide of SEQ ID NO: 12-21, classified in Class 435, subclass 7.1.

61-70. Claim 20, drawn to a method for identifying a binding partner to the polypeptide of SEQ ID NO: 12-21, classified in Class 435, subclass 23.

71-80. Claim 21, drawn to a method of screening for molecules which modify activities of the polypeptide of SEQ ID NO:12-21, classified in Class 436, subclass 86.

81-90. Claim 22, drawn to a method for preventing, treating, or ameliorating a medical condition comprising with the polypeptide of SEQ ID NO: 12-21, classified in Class 424, subclass 94.

The inventions are distinct, each from the other because of the following reasons:

3. Groups 1-10, 11-20, and 21-30 are different products. Nucleic acids, polypeptides, and antibodies to the polypeptides differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

4. Groups 31-40, 41-50, 51-60, 61-70, 71-80 and 81-90 are different methods. Methods of preventing, treating or ameliorating, methods of diagnosing, methods for identifying and methods of screening differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

6. Groups (1-10 and 31-50) and (11-20 and 51-90) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of Group 1-10 can be used for as hybridization probes or gene therapy, in addition to the methods of treating and diagnosis recited. Further, the polypeptide of Group 11-20 can be used to make antibodies, in addition to the methods of treating, screening, identifying and diagnosis recited.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter

of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.
12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
June 10, 2004

Christina Chan

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